Docket No. 22956-214
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:	
Shelby L. Cook et al.	Confirmation No. 9377
Application No. 10/615,625	Art Unit: 3731
Filed: June 27, 2003	Examiner: Tuan Van Nguyen
For: BIOABSORBABLE SUTURE ANCHOR SYSTEM FOR USE IN SMALL JOINTS	

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Dated: December 8, 2008 Signature: _____
(Ronald E. Cahill)
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APPEAL BRIEF PURSUANT TO 37 C.F.R. § 41.37

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I. REAL PARTY IN INTEREST

The real party in interest is Ethicon, Inc. of Somerville, New Jersey, which derives its rights in this application by virtue of an assignment of the application by the inventors to Ethicon, Inc. as recorded at Reel 014720, Frame 0075.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

Claims 1-5 and 8-19 are currently pending and stand rejected in the present application. Claims 6, 7, and 20-25 were previously canceled. Accordingly, claims 1-5 and 8-19 are subject to this appeal.

IV. STATUS OF AMENDMENTS

No amendments were made subsequent to the final Office Action mailed on April 23, 2008.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention provides suture anchors for anchoring tissue to a bone that are configured to toggle and anchor inside a bone cavity based on tension being applied to a suture located in a suture channel of the anchors. The suture channel is formed so that it is oriented substantially transverse at right angles to a longitudinal axis of symmetry of an elongate body of the anchor, and further, so that it is laterally offset with respect to the longitudinal axis in a direction opposite to a direction of a flared portion formed on a second, trailing end of the suture anchor. The anchor can also be included as a component of a system for anchoring tissue to a bone that further includes a length of suture thread and a suture anchor insertion tool, and additionally, the anchor can be used in a method of attaching tissue to a bone in a patient's body.

A. Independent Claim 1 Recites a Suture Anchor for Anchoring Tissue to a Bone

Independent claim 1 recites a suture anchor for anchoring tissue to a bone. By way of non-limiting examples, FIGS. 1, 2A, and 2B, which are reproduced below, illustrate one embodiment of such a suture anchor and FIGS. 3, 4A, and 4B illustrate a second embodiment of such a suture anchor. The suture anchors 10, 110 each include an elongate body 12, 112 defined by a longitudinal axis of symmetry L, a first, leading end 14, 114, and a second, trailing end 16, 116, a flared portion 24, 124 formed on the second end 16, 116, and a suture channel 32, 132 formed in the elongate body 12, 112 for passage of a suture strand therethrough. Page 5, lines 2-9 and 26-27 and page 6, lines 13-15 of the Application as filed ("the Application"). The elongate body 12, 112 includes two opposed surfaces 20, 120 between the first end 14, 114 and the second end 16, 116 and a plurality of sidewalls 22, 122 extending between the two opposed surfaces 20, 120. *Id.* at page 5, lines 6-8 and page 6, lines 13-15. The flared portion 24, 124 extends from one of the sidewalls 22, 122 and is adapted to engage and anchor into bone tissue. *Id.* at page 5, lines 8-14 and page 6, lines 13-15. The suture channel 32, 132 extends between the two opposed surfaces 20, 120, is substantially transverse at right angles to the longitudinal axis of symmetry L of the body 12, 112, and has a centerline that is laterally offset with respect to the longitudinal axis of symmetry L of the body 12, 112 in a direction opposite to the direction of the flared portion 24, 124. *Id.* at page 5, line 27 to page 6, line 15. Each of the suture anchors 10, 110 as recited is configured to toggle and anchor inside a bone cavity based on tension being applied to a suture in the suture channel 32, 132. *Id.* at page 6, lines 9-15.

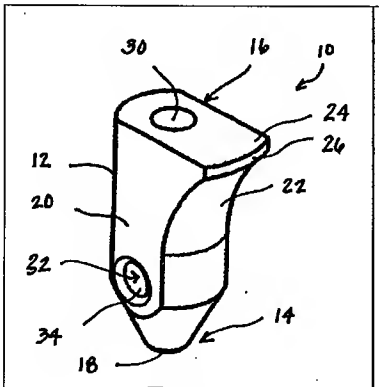


FIG. 1

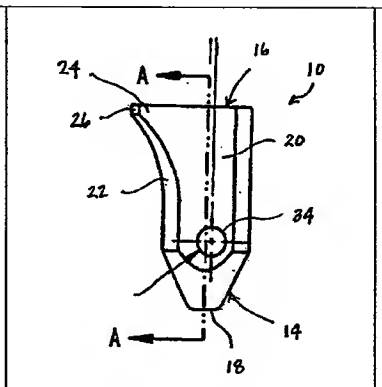
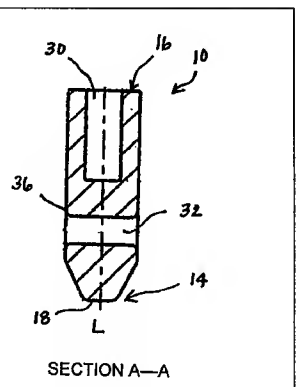


FIG. 2A



SECTION A—A
FIG. 2B

B. Independent Claim 15 Recites a System for Anchoring Tissue to a Bone

Independent claim 15 recites a system for anchoring tissue to a bone. By way of a non-limiting example, FIGS. 5A-5C, which are reproduced below with typed reference numbers, illustrate one embodiment of a system 200 that includes a bioabsorbable suture anchor 10, a length of suture thread 206 attached to the suture anchor 10, and a suture anchor insertion tool 210. *Id.* at page 10, line 4 to page 11, line 13. The suture anchor 10 includes all of the features discussed above with respect to claim 1 and further includes a bore 30 extending into the elongate body 12 from the second, trailing end 16. *Id.* at page 10, lines 4-6 and page 5, lines 21-22. The suture anchor insertion tool includes an elongate member 212 with a proximal, handle end (not shown) and a distal attachment end 214. *Id.* at page 10, lines 19-22.

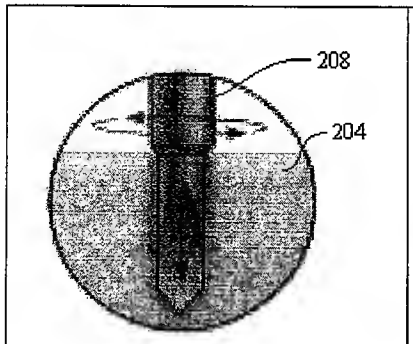


FIG. 5A

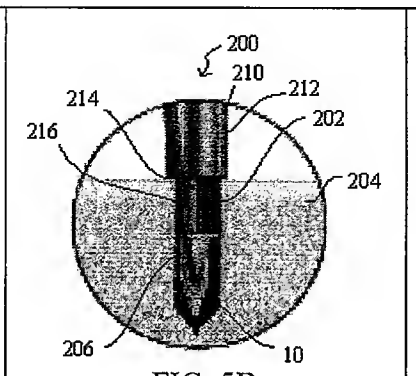


FIG. 5B

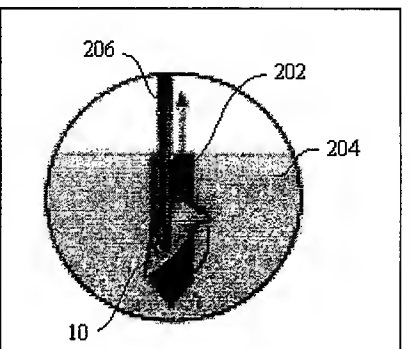


FIG. 5C

C. Independent Claim 19 Recites a Method of Attaching Tissue to a Bone

Independent claim 19 recites a method of attaching tissue to a bone in a patient's body. By way of a non-limiting example, FIGS. 6A-6C, which are reproduced below with typed reference numbers, illustrate one embodiment of a method that includes providing a system 200 for anchoring tissue to bone that includes a bioabsorbable suture anchor 10 and a length of suture thread 206 attached to the suture anchor 10, forming a bone cavity 202 in the bone where the tissue is to be anchored, securing the suture strand 206 of the system 200 to a portion of tissue to be attached to the bone, inserting the suture anchor 10 at least partially within the bone cavity 202, and toggling the suture anchor 10 by pulling on the attached suture strand 206 such that a

flared portion 24 of the anchor 10 penetrates into an inner surface of the bone cavity 202. *Id.* at page 11, lines 2-13 and 19-27. The suture anchor 10 of the system 200 includes all of the features discussed above with respect to claim 1. *Id.* at page 10, lines 4-6.

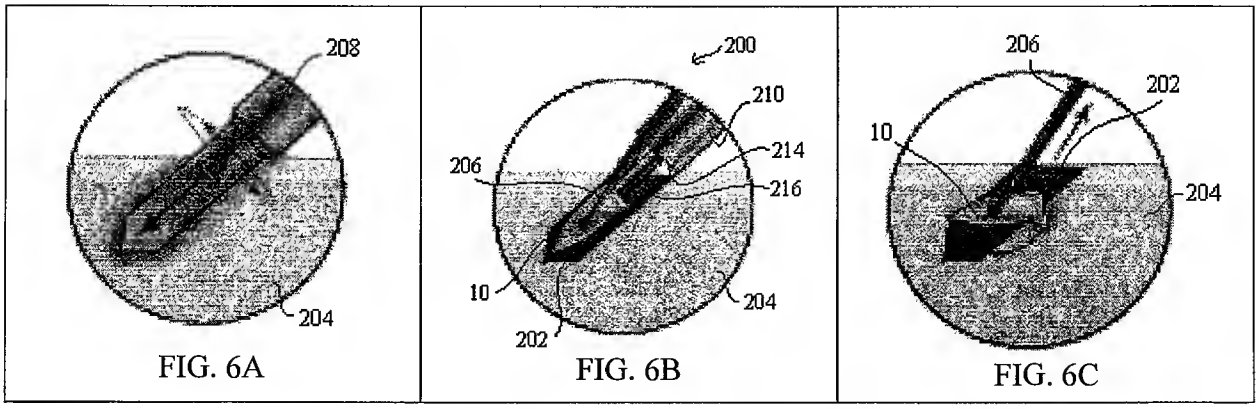


FIG. 6A FIG. 6B FIG. 6C

D. Dependent Claims 2, 3, 17, and 18 Recite Particular Dimensions of the Suture Anchor

Claim 2 recites a suture anchor 10, 110 in which a length of the elongate body 12, 112 is in the range of about 2 to about 6 mm. *Id.* at page 7, lines 5-6. Similarly, claim 17 recites a system 200 in which a length of the elongate body 12 of the suture anchor 10 is in the range of about 2 to about 6 mm. *Id.*

Claim 3 recites a suture anchor 10, 110 in which a width of the second trailing end 16, 116 is about 1 mm to about 3 mm at its widest portion. *Id.* at lines 6-7. Similarly, claim 18 recites a system 200 in which a width of the second trailing end 16 of the suture anchor 10 is about 1 mm to about 3 mm at its widest portion. *Id.*

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

There are two grounds of rejection to be reviewed on appeal.

A. Rejections Under 35 U.S.C. § 103(a) of Claims 1-5 and 8-18.

The Examiner has rejected claims 1-5 and 8-18 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,270,518 to Pedlick et al. in view of U.S. Patent No. 5,626,612 to Bartlett.

B. Rejection Under 35 U.S.C. § 102(b) of Claim 19

The Examiner has rejected claim 19 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,773,436 to Donnelly et al.

VII. ARGUMENT

Applicants traverse each of the bases for rejecting the claims.

A. To Rebut Obviousness Rejections, It Is Important to Understand the Context in which the Invention Was Made

To fully understand the claimed invention, it is first necessary to appreciate the state-of-the-art at the time of Applicants' invention, which represents the background against which the claimed invention was developed.

1. The Problem Addressed by the Invention Is the Creation of a Toggling Suture Anchor for Use in Small Bones

A number of devices and methods have been developed to attach soft tissue to bone. These include screws, staples, cement, suture anchors, and sutures alone. Some of the more successful methods involve use of a suture anchor to attach a suture to the bone, and tying the suture in a manner that holds the tissue in close proximity to the bone. Page 1, lines 22-25 of the Application.

While suture anchors for reattaching soft tissue to bone are known in the art, they are typically sized and dimensioned for use in large bone joints such as the patient's shoulder or knee. Where the need arises to reattach tissue to a relatively small bone in the patient's body, such as in the hand or the skull, the anchors currently available would be too large for the insertion depth desired. *Id.* at page 2, lines 10-14.

Suture anchors that were used in small spaces prior to the invention primarily relied upon screws, threads, and barbs to attach tissue to bone. While some forms of toggling suture anchors were known for use in large bones prior to the invention, Applicants were not aware of any suture anchors that were capable of toggling in such small spaces as the recited suture anchors

can at the time of the invention. This was because the structures in which the suture anchors were used were too small to handle the types of toggling suture anchors that were known. Prior to the present invention, it was not known how to design a suture anchor that was small enough to work in those structures and also toggle. As a result, those of ordinary skill in the art instead developed non-toggling anchors for use with such small bones, such as anchors with threads and screws. Paragraph 7, pages 3-4 of the Declaration of Jose E. Lizardi Pursuant to Rule 132 filed on January 22, 2008 ("the Declaration"); *see also* references cited in paragraph 7 on pages 3-4 of the Declaration.

Accordingly, at the time of the invention, there was a need for a suture anchor that was suitably dimensioned and configured for reattaching soft tissue to bone in small joints of a patient such as in a hand or skull that was capable of toggling. *Id.* and page 2, lines 14-16 of the Application.

2. The Invention Solves the Problem Both by Creating a Suture Anchor Capable of Toggling that Is Smaller than Those on the Market and by Configuring the Suture Channel as Claimed

The present invention solves the problem of creating a suture anchor that is capable of toggling for reattaching soft tissue to bone in small joints by engineering a suture anchor that is both smaller than anchors on the market and which includes a suture channel that is oriented to be transverse to and longitudinally offset with respect to a longitudinal axis of the body of the anchor. The claimed suture anchors, systems for anchoring tissue to a bone, and methods of attaching tissue to a bone are thus useful in a variety of different procedures, including in the repair or reconstruction of collateral ligaments, flexor and extensor tendon at the proximal interphalangeal (PIP), distal interphalangeal (DIP), and metacarpal interphalangeal (MIP) joints of all digits in a patient's hand, and for attaching soft tissue to the parietal, temporal ridge, frontal, mandible, maxilla, zygoma, and periorbital bones of the skull. The anchors, systems, and methods are particularly useful in these types of procedures because of their small size and their geometry. Paragraph 6, pages 2-3 of the Declaration.

More particularly, the anchor comprises an elongate body defined by a longitudinal axis, a first, leading end, and a second, trailing end. The elongate body also has two opposed surfaces extending between the first and second ends, and a plurality of sidewalls extending between the two opposed surfaces. The first, leading end can be tapered and extend into a blunt tip having a continuous surface, which the second, trailing end can be wider than the first end such that one of the sidewalls is flared. The suture anchor also includes a suture channel that extends between the two opposed surfaces. The suture channel is formed in the elongate body to allow the passage of a suture strand therethrough, and it is preferably oriented to be ***transverse to the longitudinal axis of the anchor***. The suture channel is flanked, or bordered, on each side by an opening that is located on an opposed surface. The center of each of the openings is ***laterally offset with respect to the longitudinal axis of the elongate body***, and in particular, the openings are laterally offset ***on the opposite side of the longitudinal axis when compared to the flared portion of the second, trailing end***. The offset channel enables a surgeon to toggle the suture anchor ***by pulling on an attached suture strand*** while the anchor is inside a bone cavity so that the flared portion toggles into the bone. *Id.* and page 2, line 19 to page 3, line 13 of the Application; *emphasis added.*

Accordingly, the present invention is directed to a toggling suture anchor that can be used to attach tissue to small bones and joints, as well as systems and methods related to the same, because the anchor is smaller than toggling suture anchors used prior to the invention and the suture channel of the anchor is configured in such a manner that toggling can occur in small bones and joints. *Id.*

B. Claims 1 and 15, as well as the Claims that Depend Therefrom, Are Not Obvious Over Pedlick in View of Bartlett

The configuration of the claimed suture anchor, which is independently claimed (claim 1) and is a portion of an independently claimed system (claim 15), and in particular the design and location of a suture channel of the claimed suture anchor, is critical to the success of the claimed invention. In particular, by forming a suture channel in an elongate body of a suture anchor that is oriented substantially transverse at right angles to a longitudinal axis of symmetry of the body and which has a centerline that is laterally offset with respect to the longitudinal axis of

symmetry of the body in a direction opposite to the direction of a flared portion of the anchor, the anchor is capable of toggling inside a bone cavity based on tension being applied to a suture in the suture channel.

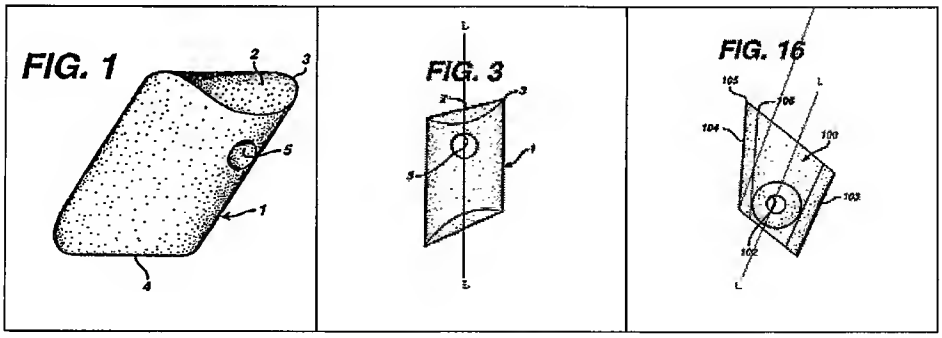
1. The Scope and Content of the Prior Art

To fully understand the obviousness rejection, it is first necessary to understand the scope and content of the cited prior art.

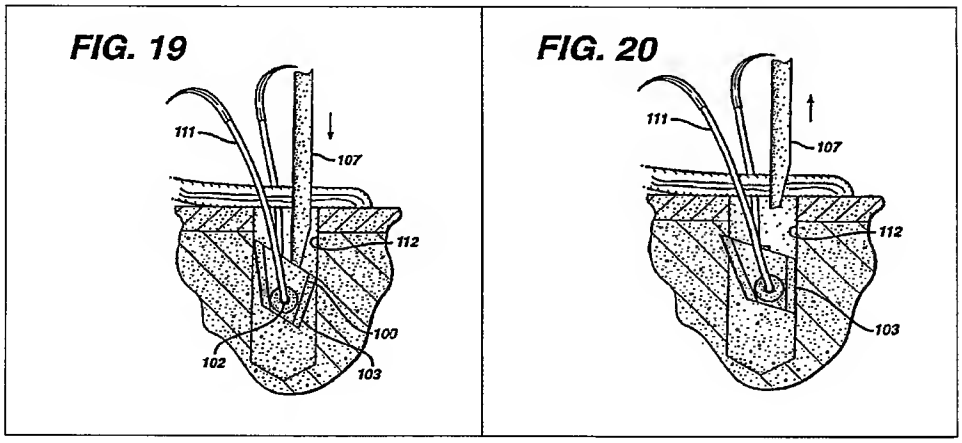
a. Pedlick Teaches a Wedge Shaped Suture Anchor in which the Suture Channel Is Aligned with the Longitudinal Axis of Symmetry of the Suture Anchor Body

U.S. Patent No. 6,270,518 to Pedlick et al. ("Pedlick") discloses a wedge shaped suture anchor for anchoring suture material to bone. Col. 1, lines 1-2 and 9-11. As shown in FIG. 1, which is reproduced below, one embodiment of a suture anchor 1 includes a first abutment end 2 and a second abutment end 3. Col. 8, lines 50-54. The suture anchor has a substantially cylindrical cross-section and the cylindrical longitudinal surface forms with the abutment end 2 a corner 4. *Id.* at lines 54-57. A suture opening 5 is defined by the body of the suture anchor 1. *Id.* at lines 60-62. In an alternative embodiment, shown in FIG. 3 and reproduced below with a longitudinal axis of symmetry of the body L added, the first abutment end 2 and second abutment end 3 are slightly tapered to a point or edge. *Id.* at lines 62-64. The suture opening 5 is formed transverse to the longitudinal direction of the suture anchor 1, and as shown below, is aligned with a longitudinal axis of symmetry of the body L. *Id.* at lines 65-67. In yet another embodiment, shown in FIG. 16 and reproduced below with both a longitudinal axis of symmetry of the body L and a line that defines the elongate body from the flared portion so that the axis of symmetry for the body can be determined added, a suture anchor 100 has a body formed in a substantially truncated wedge shape. Col. 9, lines 63-65. The body defines a suture opening 102 and includes an abutment wall 103 and a plow wall 104 that forms an edge 105 at its intersection with top 106 of the anchor 100. Col. 9, line 65 to col. 10, line 12. As shown below, the suture opening 102 is aligned with a longitudinal axis of symmetry of the body L. The axis of symmetry of the body L is drawn to define symmetry of the body, excluding the edge 105 in

light of the longitudinal axis of symmetry of the elongate body of the claimed invention, which is determined without consideration of the flared portion. Further, a length of the top 106 is about 4.6 millimeters, the abutment wall 103 has a length of about 3.2 millimeters, and the plow wall 104 has a length of about 3.6 millimeters. Col. 11, lines 59-62.



Pedlick also discloses a method of implanting a wedge shaped suture anchor for anchoring suture material to bone. Col. 1, lines 1-2 and 9-11. As shown in FIG. 19, which is reproduced below, the suture anchor 100 has a shaft 107 attached thereto and is inserted into a bore hole after threading a suture 111 through the suture opening 102. Col. 11, lines 40-44. After the suture anchor 100 is positioned at a desired location in the hole and an applier is inserted, the shaft 107 is drawn upward, as shown in FIG. 20, which is reproduced below, forcing the edge 105 (not labeled) to dig into the softer cancellous layer of the bone. *Id.* at lines 44-50. The resulting rotation of the body of the suture anchor, in combination with the withdrawal tension, breaks a frangible portion to allow the shaft 107 to separate from the anchor 100, thereby permitting removal of the shaft 107. *Id.* at lines 50-54.



b. Bartlett Teaches an Apparatus for Anchoring Sutures in which a Location of the Suture Channel Is Configured to Have the Smallest Effect on the Strength of the Suture Anchor

U.S. Patent No. 5,626,612 to Bartlett ('Bartlett") discloses an apparatus for anchoring sutures to a live human bone. Col. 1, lines 10-11. As shown in FIG. 7, which is reproduced below, in one embodiment a suture anchor 722 has an elongate shape of a two cone combination in which a "central axis" is formed between the apex of the cone and the center of the fixed curve that forms the directrix of the cone. Col. 4, lines 49-62. The anchor 722 includes a first conical surface 740, a central axis 25, an anchor bore 34 across the conical surface, and a base that includes a second conical surface 742 inverted with respect to the first conical surface. Col. 7, lines 60-67. The anchor bore 34 is for positioning an insertion tool therein to insert the suture anchor into the patient bone hole. Col. 6, lines 54-56. The suture may be threaded through the anchor bore 34 alongside the insertion tool. Col. 7, lines 4-6. Alternatively, a separate suture accessory bore 36 may be formed substantially perpendicular to the anchor bore 34 for separately accommodating the suture. *Id.* at lines 7-10. The accessory bore 36 minimizes contact between the suture and the insertion tool during the insertion process. Col. 8, lines 44-50. As detailed by Bartlett:

> The location of accessory bore 36 is ***selected to have the smallest effect on the strength of the suture anchor*** because of the deficit of suture anchor material. One of ordinary skill in the art can determine, by routine experimentation and an analysis of the geometry of the suture anchor, the optimum point at which accessory bore 36 can be placed ***without detrimentally effecting the strength of the suture anchor.***

Id. at lines 53-60; *emphasis added.* A length of the suture anchor is approximately 1.156 cm, and a diameter is preferably approximately 0.297 cm. Col. 5, lines 31-36.

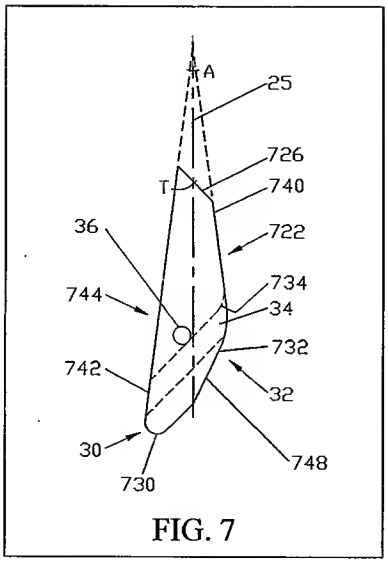


FIG. 7

Bartlett also discloses a method for anchoring sutures to a live human bone. Col. 1, lines 10-11. A suture anchor 20 (although the specification discusses the method with respect to anchor 20, col. 10, lines 46-49 indicates that anchor 722 can be used in the method) is mounted on an insertion end 44 of an insertion tool 40 by securely positioning the insertion end 44 within the anchor bore 34. Col. 10, lines 60-67. The anchor 20 is inserted into a patient bone hole 70, and once the conical surface extending between a leading edge 30 and an apex 24 encounters the patient bone hole 70, the suture anchor 20 begins to rotate or reorient in order to fit into the patient bone hole 70. Col. 11, lines 10-20. A main body 42 of the insertion tool 40 is maintained parallel to the patient bone hole 70, and thus, when the suture anchor 20 reorients, the insertion end 44 bends. *Id.* at lines 20-23. As the suture anchor 20 continues to be inserted into the bone hole 70, eventually a trailing edge 32 of the anchor 20 bypasses a cortical bone tissue 74 and begins traveling through cancellous bone tissue 76 surrounding the bone hole 70, thereby allowing the insertion end 44 of the insertion tool 40 to begin resuming its initially straight configuration and deploying the suture anchor. *Id.* at lines 24-33. Once the apex 24 clears the cortical bone tissue 74, the entire suture anchor is in cancellous bone tissue 76 and the insertion end 44 returns to its original configuration. *Id.* at lines 34-37. The suture anchor 20 can then be secured in its final position and then the insertion tool 40 can be disengaged from the suture anchor and removed. *Id.* at lines 37-42.

c. The Examiner Argues that Bartlett Remedies the Deficiencies of Pedlick by Disclosing a Suture Channel that is Laterally Offset from the Longitudinal Axis of the Anchor

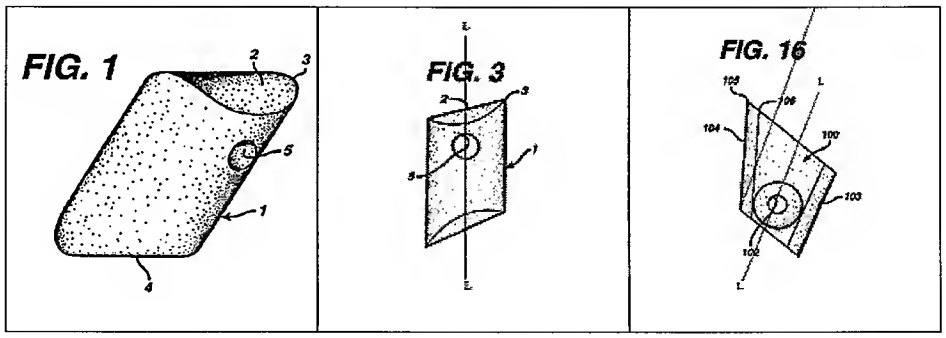
The Examiner argues that Pedlick discloses the invention substantially as claimed except for a suture channel that is laterally offset from the longitudinal axis of the anchor in a direction opposite the direction of the flared portion. Paragraph 14, lines 6-8 of page 5 of the Office Action dated April 23, 2008 ("the Office Action"). The Examiner relies on Bartlett to overcome the deficiencies of Pedlick. *Id.* at lines 8-13. In making the rejection, the Examiner argues that Pedlick does disclose a suture opening or channel 5, as shown in FIG. 1, that is offset from the center of the anchor for the purpose of toggling the anchor and that Bartlett discloses a suture anchor that includes a suture channel 36 that is laterally offset from the longitudinal axis of the anchor. *Id.* Stating that it would have been obvious to substitute one known element for another, the Examiner argues that it would have been obvious to substitute the hole of the Pedlick device with the hole disclosed by Bartlett such that the hole is offset from the center of the anchor ***for the purpose of toggling the anchor and preventing a detrimental effect on the strength of the suture anchor***. *Id.* at lines 15-21; *emphasis added.* Further, the Examiner also states that Applicants have failed to disclose that the recited suture channel provides an advantage or solves a stated problem. *Id.* at page 5, line 21 to page 6, line 1.

2. *Pedlick in View of Bartlett Fails to Render Obvious Independent Claims 1 and 15*

Independent claims 1 and 15, as well as claims 2-5, 8-14, and 16-18 which depend therefrom, are patentable over Pedlick in view of Bartlett at least because the Examiner's proposed combination does not teach or even suggest the claimed invention, there is no rational reason to make the Examiner's proposed combination, and in light of secondary considerations it cannot be said that the claimed invention was obvious at the time of the invention.

a. Pedlick in View of Bartlett Fails to Teach or Even Suggest a Suture Channel Having a Centerline that Is Laterally Offset with Respect to the Longitudinal Axis of Symmetry of the Body in a Direction Opposite to the Direction of the Flared Portion

The suture anchor of claim 1 and of the system for anchoring tissue to a bone of claim 15 both recite a suture channel having a centerline that is laterally offset with respect to the longitudinal axis of symmetry of the body in a direction opposite to the direction of the flared portion. The Examiner agrees that Pedlick fails to teach or even suggest a suture anchor having a suture channel as recited in either claim 1 or 15. Paragraph 14, lines 6-8 of page 5 of the Office Action. To the extent that Pedlick does teach that the suture opening or channel 5 is offset from the center, such as the Examiner proposes by relying on FIG. 1, which is reproduced below, it is not ***laterally*** offset as clearly illustrated in the reproductions of FIG. 3 (which is a front view of the suture anchor of FIG. 1) and FIG. 16, which are also reproduced below. A longitudinal axis of the body of the suture anchor L directly intersects the centerline of the suture opening or channel 5, contrary to the recited suture channel.



Assuming for the sake of argument that there is motivation to combine the teachings of Bartlett to substitute the suture opening 5 of Pedlick for the suture channel 36 of Bartlett, such a combination still does not teach or even suggest the claimed invention. Not only does the recited suture channel need to be laterally offset with respect to the longitudinal axis of symmetry of the body, it has to be located ***in a direction opposite to the direction of the flared portion***. The anchor of Bartlett fails to teach or even suggest a flared portion as recited in claims 1 and 15. The only portions of Bartlett that could conceivably be considered a flared portion are its leading edge 730 and its trailing edge 732, but there are not two opposed surfaces therebetween and a

plurality of sidewalls extending between the two opposed surfaces as required by the claims. Without a teaching of a flared portion as recited in claims 1 and 15, Bartlett cannot teach or even suggest a suture channel that is laterally offset with respect to the longitudinal axis of symmetry of the body ***in a direction opposite to the direction of the flared portion***.

To the extent that Bartlett does teach where to place the channel, it suggests that the channel be placed so as to "have the smallest effect on the strength of the suture anchor." In Applicants' claimed anchor, this would presumably be toward (rather than away from as claimed) the flared portion as there is more mass of material there. Thus, to the extent that Bartlett can be said to teach anything about the location of the suture channel in a flared anchor, it teaches the ***opposite*** of what is claimed.

Accordingly, at least because the proposed combination does not lead to the recited configuration of a suture anchor having a suture channel having a centerline that is ***laterally offset*** with respect to the longitudinal axis of symmetry of the body ***in a direction opposite to the direction of the flared portion***, the Examiner's proposed combination does not render independent claims 1 and 15 obvious.

b. Pedlick in View of Bartlett Fails to Teach or Even Suggest a Suture Anchor Configured to Toggle and Anchor Inside a Bone Cavity Based on Tension Being Applied to a Suture in the Suture Channel

The suture anchor of claim 1 and of the system for anchoring tissue to a bone of claim 15 both recite that the suture anchor is configured to toggle and anchor inside a bone cavity ***based on tension being applied to a suture in the suture channel***. The Examiner argues that Pedlick discloses a suture anchor that is configured to toggle and anchor inside a bone cavity by the suture. Paragraph 13, lines 23-24 of page 4 of the Office Action. The teachings of Pedlick disclose nothing of this nature.

Pedlick teaches a wedge-shaped suture anchor that is adapted to receive an installation tool for insertion into a bone hole. In use, the user applies a downward pressure to the installation tool to position the anchor within the bone hole. Once positioned, the user ***releases*** this downward pressure in preparation for withdrawing the device, causing the shaft of the tool to

straighten. This straightening force causes one of the edges of the anchor to press into the wall of the bone cavity. ***As a result***, the anchor pivots or rotates within the bone hole such that the anchor securely engages the wall of the one hole. Col. 11, lines 40-54; *emphasis added.* This method is further described in detail at col. 19, lines 33-41:

> Next, the user withdraws installation tool 400 from bore hole 600. As downward pressure on installation tool 400 is released (to be replaced by opposite upward pressure during tool withdrawal), the flexed shaft tip 404 tries to straighten itself, causing the suture anchors sharp, well-defined biting edge 322 to press into wall 602, and causing the suture anchor to pivot slightly in the bore hole so that the suture anchor's cam surface 326 securely engages wall 606 of the bore hole. As the user retracts installation tool 400 from bore hole 600, rearward movement of installation tool 400 causes progressively more distal portions of the suture anchor's cam surface 326 to come into engagement with wall 606 of the bore hole.

See also, col. 9, lines 17-38 (for the embodiment illustrated in FIGS. 9 and 10), col. 9, lines 39-62 (for the embodiment illustrated in FIGS. 11 and 12), col. 11, lines 40-56 (for the embodiment illustrated in FIGS. 19-25), and col. 12, lines 61-65 (for the embodiment illustrated in FIG. 26). ***In every one of the many embodiments in Pedlick, it is the installation tool that rotates the anchor.***

The Examiner also asserts that Pedlick discloses a suture opening or channel that is offset from the center of the anchor "for the purpose of toggling the anchor." Paragraph 14, lines 8-11 of page 5 of the Office Action. The Pedlick anchor's offset, however, is never laterally offset as recited. To the extent that Pedlick teaches that the suture channel 5 can be longitudinally offset from the center, it teaches that this configuration creates an imbalance in the rotation of the device on implantation that makes it easier for the ***inserter tool*** to impart rotation to the anchor. Col. 8, line 67 to Col. 9, line 38. Thus, rather than teaching a configuration for toggling based on tension from a suture in the channel, Pedlick teaches a configuration that promotes toggling by the inserter tool. Pedlick teaches neither Applicants' structure nor Applicants' function.

Bartlett fails to remedy the deficiencies of Pedlick because it too relies on an insertion tool to toggle and anchor the suture anchor inside a bone cavity. In use, the user mounts the insertion end of the insertion tool into the anchor bore of the anchor and inserts the combination into a patient bone hole. As the anchor progresses in the bone hole, the anchor begins to rotate or reorient, and while the main body of the insertion tool remains parallel to the bone hole, the insertion end of the insertion tool bends. Eventually the anchor is fully disposed in the bone hole, thereby allowing the insertion end of the insertion tool to return to its initially straight configuration and deploy the suture anchor. Once the suture anchor is secured in its final position, the insertion tool is disengaged from the suture anchor and removed. Col. 11, lines 10-42.

Accordingly, further because neither Pedlick nor Bartlett, either alone or in combination, teaches or even suggests a suture anchor that is configured to toggle and anchor inside a bone cavity based on tension being applied to a suture in the suture channel, the Examiner's proposed combination does not render independent claims 1 and 15 obvious.

c. There Is No Suggestion or Motivation to Combine Bartlett with Pedlick

While the combination of Pedlick and Bartlett fails to teach or even suggest multiple recitations of independent claims 1 and 15, the Examiner's rejection fails further because there is no rational underpinning for making the combination proposed by the Examiner.

In accordance with the procedures outlined by the Manual of Patent Examining Procedure (MPEP) in light of *KSR International Co. v. Teleflex Inc.*, there must be one or more clearly articulated reasons as to why the claimed invention would have been obvious in order to support any rejection under 35 U.S.C. §103.

> The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. __, __, 82 USPQ2d 1385, 1396 (2007) notes that the analysis supporting a rejection under 35 U.S.C. 103 ***should be made explicit***. The Federal Circuit

> has stated that "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there ***must be some articulated reasoning with some rational underpinning*** to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). See also *KSR*, 550 U.S. at __, 82 USPQ2d at 1396 (quoting Federal Circuit statement with approval.)

MPEP § 2142; *emphasis added.* Moreover, the Examiner must guard against impermissible hindsight that results from the knowledge of the invention of the present application and the Examiner may not "use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious." *In re Kotzab*, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) (citation omitted).

Neither Pedlick nor Bartlett provides any suggestion or motivation for the Examiner's proposed combination of substituting the suture opening or channel 5 of the Pedlick anchor with the suture accessory bore 36 of the Bartlett anchor such that the bore is offset from the center of the anchor in a direction opposite the direction of the flared portion. The Examiner asserts that a person of ordinary skill in the art would have been motivated to make such a substitution both for the purpose of toggling the anchor and preventing a detrimental effect on the strength of the suture anchor. Paragraph 14, lines 15-21 of page 5 of the Office Action. As discussed in section VII(B)(2)(b) above, neither Pedlick nor Bartlett teach a laterally offset suture channel or bore "for the purpose of toggling the anchor." The suture opening or channel 5 of the Pedlick anchor is not laterally offset at all, and, presumably, the anchor is sufficiently strong for its intended purpose.

Likewise, Bartlett also does not teach a laterally offset suture channel or bore "for the purpose of toggling the anchor," as its anchor, like Pedlick's anchor, is toggled by the insertion tool. According to Bartlett, "[t]he location of accessory bore 36 is selected to have the smallest effect on the strength of the suture anchor because of the deficit of suture anchor material." Col. 8, lines 53-56. This makes sense in the context of Bartlett, as can be seen in FIGS. 3 and 4, which are reproduced below, because Bartlett provides a through-bore (34) at an angle through

the anchor body for mating with the insertion tool – the placement of the suture bore (36) would need to be driven by concerns about integrity.

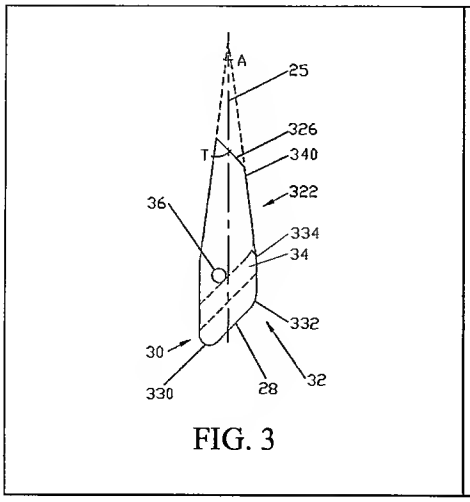


FIG. 3

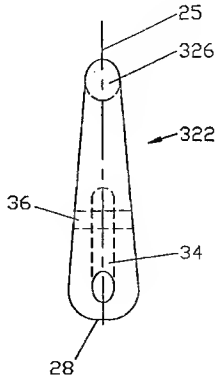


FIG. 4

In sharp contrast to the situation in Bartlett, Pedlick does not weaken its anchor body by providing a through-bore for attachment to an insertion tool. As a result, Pedlick places its suture holding bore right on the longitudinal axis of the suture body (that is, the portion of the anchor that is not the "flared portion"), as this would be where the most material is. Accordingly, "the strength of the suture anchor" is not a rational basis for moving Pedlick's suture bore laterally from the longitudinal axis as this would only make Pedlick's suture body weaker. Still further, if one were motivated to move Pedlick's suture bore off-axis for reasons of strength of the suture anchor, a person of ordinary skill would be motivated to move it ***toward*** the flare as there is more material there rather than in the ***opposite*** direction as is expressly recited in the claim.

In summary, the Examiner posits two reasons for modifying Pedlick. One reason is "the strength of the suture anchor." This reason is at best not rational, and would actually motivate a person of ordinary skill to do the opposite of what is recited in the claim. The second reason for moving the suture bore off-axis, so that the suture can toggle the anchor, can be found only in Applicants' specification and nowhere else in the art. This is the very definition of hindsight reasoning using Applicants' invention as a template to pick and choose features from the art. *KSR* prohibits this. Accordingly, there is no motivation to make the proposed modification.

d. The Claimed Suture Anchor and System for Anchoring Tissue to a Bone Is Not Obvious in View of Secondary Considerations

The fact that the proposed combination is not obvious is further supported by secondary considerations such as the previously unachieved advantages that result from the claimed invention and the commercial success that has resulted from the same.

The Examiner asserts that no advantage is achieved or problem solved by forming a suture channel in the elongate body of an anchor having a centerline that is laterally offset with respect to the longitudinal axis of symmetry of the body in a direction opposite to the direction of the flared portion of the anchor. Paragraph 14, page 5, line 21 to page 6, line 3 of the Office Action. This assertion, however, completely ignores the Declaration in which one of the inventors, Jose E. Lizardi, explains the advantages that were achieved and the problems that were solved as a result of the present invention.

Prior to the present invention, the use of suture anchors in small bones were limited primarily to suture anchors that used screws, threads, and barbs to attach tissue to bone. Paragraph 7, page 3, lines 5-6 of the Declaration While toggling anchors were known at the time of the invention, they were used in larger bones, such as bones of the shoulder disclosed for procedures described in Pedlick. *Id.* at page 4, lines 1-7 of the Declaration. A goal the inventors sought to achieve, and which was successfully achieved as a result of the present invention, was to develop a smaller toggling anchor that could bring the advantages in ease of use and grip in bone of toggling anchors to procedures in smaller bones that lacked the space for such toggling anchors in the past. By using the claimed configuration, an advantage was achieved because the anchor could be toggled simply by putting tension on the suture thread – using the anchor inserter to toggle the anchor was not required (and indeed, there would not be room for it) – and having the anchor toggle in a predetermined direction and way by placing the suture channel in its recited transverse and offset configuration. A further advantage was achieved because the toggling could be directed, therefore allowing a surgeon to plan for the directed toggling and choosing an orientation of the bone hole in which there was sufficient room for the anchor to toggle, even within small bone spaces. *See id.* at paragraphs 4, 6, and 7. As a result of the

present invention, no longer were screws, threads, and barbs needed to attach tissue to bone in procedures for small bones, but rather, togging anchors could now be used. Thus, despite the Examiner's assertions, the present invention both provides an advantage over anchors that were previously used in procedures for small bones,[1] and solves a problem of not being able to use toggling anchors in small bones.

The fact that the present invention both provides advantages over the prior art and solves problems that existed in the field is further supported by the commercial success experienced by suture anchors that are still sold using the claimed configuration. The commercial success of a claimed invention is a secondary consideration that, when presented, is evaluated in determining whether the claimed invention was obvious. *See* MPEP § 716. Commercial success is an indicator that an invention may not be obvious provided that there is a nexus between the claimed invention and the commercial success. MPEP § 716.03.

Following the present invention, in 2003 the assignee of the present application released two products based upon the claimed design, the MiniLok and MicroFix suture anchors. Paragraph 8, page 4, lines 9-11 of the Declaration. The marketing and sales for the suture anchors were performed in the normal course of business, and the suture anchors have sold well since that time and are still offered for sale today, in particular for uses with surgeries involving the attachment of tissue to bones in the hand and face (i.e., small bones). *Id.* at lines 11-14 and 17-18. "Doctors and others purchasing the suture anchors prefer the toggling suture anchors for such use as opposed to the thread or screw suture anchors because the toggling causes less damage to the bone and causes a more secure and exact fit between the tissue and the bone the tissue is being attached to." *Id.* at lines 14-17. "The commercial success of the suture anchors continue even today as the advantages provided by the first toggling suture anchors for use in small areas such as bones in the hand and face are still realized and appreciated as an industry standard." *Id.* at lines 18-21.

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[1] Although the Examiner asserts that the Pedlick and Bartlett anchors are configured for use in small bones, the references and the Declaration make clear that they are not configured for such use, and thus, they would not perform equally well as the Examiner argues.

Accordingly, further evidence of nonobviousness is provided by achieved advantages, problems solved, and commercial success that resulted from the claimed configuration of a suture anchor.

Thus, in light of the fact that the Examiner's proposed combination does not lead to the claimed invention, that there is no suggestion or motivation to make the Examiner's proposed combination, and that the secondary considerations further support the fact that the claimed invention is not obvious, claims 1 and 15, as well as claims 2-5, 8-14, and 16-18 which depend therefrom, distinguish over the combination of Pedlick and Bartlett and represent allowable subject matter.

3. Pedlick in View of Bartlett Further Fails to Render Obvious Dependent Claims 2, 3, 17, and 18

Claims 2, 3, 17, and 18 are patentable at least because they depend from allowable base claims 1 and 15, however, they are further patentable because the limitations of each of claims 2, 3, 17, and 18 are not taught or suggested by either Pedlick or Bartlett, either alone or in combination.

a. Pedlick in View of Bartlett Fails to Teach or Even Suggest a Suture Anchor in which the Elongate Body Is in the Range of about 2 to about 6 mm

Dependent claim 2 is further patentable over Pedlick in view of Bartlett because neither reference teaches or even suggests a suture anchor in which a length of the elongate body of the anchor is in the range of about 2 to about 6 mm. The Examiner argues that Pedlick discloses a suture anchor that has a 3 mm diameter and a suture anchor that has an overall size that is smaller than conventional bone anchors. Paragraph 15, lines 4-6 of page 6 of the Office Action. The Examiner, relying on *In re Aller*, also argues that determining the optimum or workable range of a claim where the general conditions of a claim are disclosed involves only routine skill in the art. *Id.* at lines 6-12. Relying on extrinsic evidence, the Examiner asserts that U.S. Patent No. 6,280,474 to Cassidy ("Cassidy") discloses a bone anchor that can be used to attach small

bone to small bone or soft tissue to bone in which a length is between 3 mm and 30 mm. *Id.* at lines 12-16.

While Pedlick does disclose a suture anchor having a ***diameter*** of 3 mm, the section that the Examiner argues includes a disclosure that the suture anchor has an overall size that is smaller than conventional bone anchors, i.e., col. 9, lines 20-25, states nothing of the sort. In fact, as discussed at length throughout this brief, the present invention is particularly advantageous because it recites a toggling suture anchor that can be used in small bones, unlike the cited prior art references which toggle in larger bones. Further, while the ***diameter*** of the suture anchor 1 in Pedlick, which is defined by a length of the abutment end 2, may be 3 mm, the length of the elongate body, which is defined by a full length of the body, is larger. *See* col. 9, lines 23-26. In particular, Pedlick discloses that the hole in which the suture anchor 1 is disposed has a diameter of 5 mm, and as illustrated in FIGS. 9 and 10, which are reproduced below, the length of the body is approximately greater than the diameter of the bone hole because the ends of the anchor 1 extend outside of the hole and into the softer cancellous layer surrounding the hole. *Id.* Thus, Pedlick fails to teach or even suggest a suture anchor having an elongate body with a length in the range of about 2 to about 6 mm.

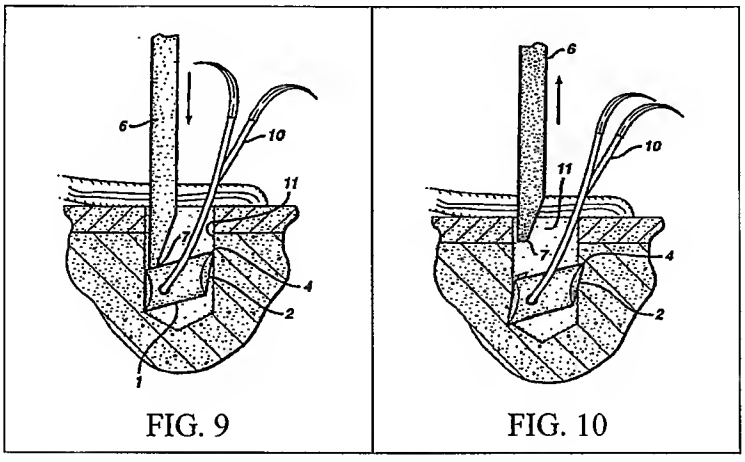

FIG. 9 FIG. 10

Bartlett fails to remedy the deficiencies of Pedlick. Bartlett teaches that the length of suture anchors 20, 22, 322, and 722 is preferably approximately 1.156 cm and the length of suture anchor 522 is preferably approximately 1.118 cm. Col. 5, lines 31-34. Both of these lengths are significantly larger than the recited range of about 2 to about 6 mm.

Still further, the reliance by the Examiner on *In re Aller* is inapt. As § 2144.05(II)(B) of the MPEP notes:

> A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).*

The Examiner provides no indication that the length of the elongate body is a result-effective variable. Neither Pedlick nor Bartlett recognize or suggest that a length of the elongate body of the anchor is a result-effective variable. The Examiner asserts that Cassidy discloses a bone anchor that can be used to attach small bone to small bone or soft tissue to bone in which a length is between 3 mm and 30 mm, but Cassidy too fails to recognize this parameter as a result-effective variable. Without a determination that a parameter is a result-effective variable, an optimum or workable range ***cannot*** be determined through routine experimentation, and thus a rejection on these grounds cannot be sustained.

The Examiner's reliance on Cassidy is also improper because a person of ordinary skill in the art would not rely on the teachings of Cassidy, which are directed to a device that swells in order to implant in bone, to modify the teachings of anchors that toggle, like the anchors of Pedlick and Bartlett. Cassidy teaches an implant made of a dehydrated, resorbable, swellable preformed body that, after insertion, anchors in hard tissue when the implant rehydrates and swells. Col. 8, lines 16-24. Regardless of the dimensions taught by Cassidy, the teachings are inapplicable to a toggling suture anchor. There is no plausible way to rely on the teachings of a swelling implant as described in Cassidy to arrive at a toggling suture anchor that has a length of an elongate body that is in the range of about 2 to about 6 mm. Any teachings from Cassidy cannot be combined with the teachings of either Pedlick or Bartlett to arrive at the claimed dimensions.

Accordingly, dependent claim 2 is further patentable over any combination of Pedlick, Bartlett, and Cassidy because none of the possible combinations teach or even suggest a suture

anchor configured to toggle in which a length of the elongate body of the anchor is in the range of about 2 to about 6 mm.

b. Pedlick in View of Bartlett Fails to Teach or Even Suggest a System for Anchoring Tissue to Bone that Includes a Suture Anchor in which the Elongate Body of the Suture Anchor Is in the Range of about 2 to about 6 mm

Similarly, dependent claim 17 is further patentable over Pedlick in view of Bartlett because neither reference teaches or even suggests a system for anchoring tissue to bone that includes a suture anchor in which a length of the elongate body of the anchor is in the range of about 2 to about 6 mm. The Examiner also suggests that Cassidy discloses the claimed length range. As discussed above with respect to claim 2, none of Pedlick, Bartlett, and Cassidy, either alone or in combination, teach or even suggest a suture anchor in which a length of the elongate body of the anchor is in the range of about 2 to about 6 mm. Further, the determination of the optimum or workable range of the claimed length does not involve only routine skill in the art because such determination is not made based on a result-effective variable. Accordingly, dependent claim 17 is further patentable over any combination of Pedlick, Bartlett, and Cassidy.

c. Pedlick in View of Bartlett Fails to Teach or Even Suggest a Suture Anchor in which a Width of the Second Trailing End Is about 1 mm to about 3 mm at Its Widest Portion

Dependent claim 3 is further patentable over Pedlick in view of Bartlett because neither reference teaches or even suggests a suture anchor in which a width of the second trailing end of the anchor is about 1 mm to about 3 mm at its widest portion. The Examiner argues that Pedlick discloses a suture anchor that has a 3 mm diameter and a suture anchor that has an overall size that is smaller than conventional bone anchors. Paragraph 15, lines 4-6 of page 6 of the Office Action. The Examiner, relying on *In re Aller*, also argues that determining the optimum or workable range of a claim where the general conditions of a claim are disclosed involves only routine skill in the art. *Id.* at lines 6-12. Relying on extrinsic evidence, the Examiner asserts that Cassidy discloses a bone anchor that can be used to attach small bone to small bone or soft tissue to bone in which a width is between 1 mm and 6 mm. *Id.* at lines 12-16.

As explained above in section VII(B)(3)(a), the section of Pedlick that the Examiner argues includes a disclosure that the suture anchor has an overall size that is smaller than conventional bone anchors, i.e., col. 9, lines 20-25, does not include such a statement or implication. While a suture anchor that has an overall size that is smaller than conventional toggling bone anchors is a distinct feature of the present invention, Pedlick does not provide any such teachings. Pedlick does disclose a suture anchor having a diameter of 3 mm, but this is considerably larger than the recited range of widths of the trailing edge – 1 mm to about 3 mm at its widest portion. *See* col. 9, lines 23-26 of Pedlick.

Bartlett fails to remedy the deficiencies of Pedlick. Bartlett teaches that the thickest diameter of the suture anchors 20, 22, 322, and 722 is preferably approximately 0.297 cm and the diameter of the cylindrical portion of suture anchor 522 is preferably approximately 0.287 cm. Col. 5, lines 35-38. Both of these diameters are significantly larger than the recited range of about 1 mm to about 3 mm at its widest portion.

Further, similar to determining the length of the elongate body of the anchor, determining the optimum or workable range of the claimed width also does not involve only routine skill in the art because such determination is not a result-effective variable. The Examiner provides no indication that the width of the second trailing end is a result-effective variable. Neither Pedlick nor Bartlett recognize or suggest that a width of the second trailing end is a result-effective variable. The Examiner asserts that Cassidy discloses a bone anchor that can be used to attach small bone to small bone or soft tissue to bone in which a width is 1 mm to about 6 mm, but Cassidy too fails to recognize this parameter as a result-effective variable. Without a determination that a parameter is a result-effective variable, an optimum or workable range cannot be determined through routine experimentation, and thus a rejection on these grounds cannot be sustained.

The Examiner's reliance on Cassidy with respect to the claimed width is also improper because a person of ordinary skill would not rely on the teachings of the swellable implant of Cassidy to modify the teachings of anchors that toggle, like the anchors of Pedlick and Bartlett. Regardless of the dimensions taught by Cassidy, the teachings are inapplicable to a toggling

suture anchor. There is no plausible way to rely on the teachings of a swelling implant as described in Cassidy to arrive at a toggling suture anchor that has a width of the second trailing end that is about 1 mm to about 3 mm at its widest portion. Any teachings from Cassidy cannot be combined with the teachings of either Pedlick or Bartlett to arrive at the claimed dimensions.

Accordingly, dependent claim 3 is further patentable over any combination of Pedlick, Bartlett, and Cassidy because none of the possible combinations teach or even suggest a suture anchor configured to toggle in which a width of the second trailing end of the anchor is about 1 mm to about 3 mm at its widest portion.

d. Pedlick in View of Bartlett Fails to Teach or Even Suggest a System for Anchoring Tissue to Bone that Includes a Suture Anchor in which a Width of the Second Trailing End of the Suture Anchor Is about 1 mm to about 3 mm at Its Widest Portion

Similarly, dependent claim 18 is further patentable over Pedlick in view of Bartlett because neither reference teaches or even suggests a system for anchoring tissue to bone that includes a suture anchor in which a width of the second trailing end of the anchor is about 1 mm to about 3 mm at its widest portion. The Examiner also suggests that Cassidy discloses the claimed width range. As discussed above with respect to claim 3, none of Pedlick, Bartlett, and Cassidy, either alone or in combination, teach or even suggest a suture anchor in which a width of the second trailing end of the anchor is about 1 mm to about 3 mm at its widest portion. Further, the determination of the optimum or workable range of the claimed width does not involve only routine skill in the art because such determination is not made based on a result-effective variable. Accordingly, dependent claim 18 is further patentable over any combination of Pedlick, Bartlett, and Cassidy.

C. Claim 19 Is Not Anticipated by Donnelly

The configuration of the suture anchor, which directly affects the independently claimed method, and in particular the design and location of a suture channel of the claimed suture anchor, is critical to the success of the claimed invention. In particular, by forming a suture channel in an elongate body of a suture anchor that is oriented substantially transverse at right

angles to a longitudinal axis of symmetry of the body and which has a centerline that is laterally offset with respect to the longitudinal axis of symmetry of the body in a direction opposite to the direction of a flared portion of the anchor, the anchor is capable of toggling inside a bone cavity based on tension being applied to a suture in the suture channel.

1. The Scope and Content of the Prior Art

To fully understand the anticipation rejection, it is first necessary to understand the scope and content of the cited prior art.

a. Donnelly Discloses an Absorbable Bone Anchor in which the Suture Channel Is Obliquely Angled to Allow the Bone Anchor to Toggle in Two Planes

Donnelly discloses a bioabsorbable bone anchor system for attaching soft tissue to hard bone. Col. 1, lines 14-17. As shown in FIGS. 1A and 1B, which are reproduced herein with reference label L added to FIG. 1B, one embodiment of a bone anchor 10 includes an elongate body 12 extending between a first leading end 14 and a second trailing end 16 for defining a longitudinal axis L. Col. 3, lines 43-46. The elongate body 12 includes two opposed surfaces 18 that extend between the ends 14, 16, a plurality of sidewalls 20 adjacent to and extending between the two opposed surfaces, and a suture channel 24 for passage of a suture strand through the bone anchor 10. *Id.* at lines 47-51 and 66-67. The suture channel 24 includes a through-hole extending through each of the opposed surfaces 18 and into recessed openings 28 at each of the surfaces 18. Col. 3, line 67 to col. 4, line 5. The suture channel 24 is ***obliquely angled*** with respect to the longitudinal axis L of the body 12 such that the recessed openings 28 of the suture channel 24 on opposed surfaces 18 do not line up. Col. 4, lines 12-16; *emphasis added.* "***Because of the uniquely angled suture channel 24*** of bone anchor 10, a suture strand extending through this channel 24 can effect a toggling action in the bone anchor 10 ***in two planes*** when tension is applied." *Id.* at lines 17-20; *emphasis added.*

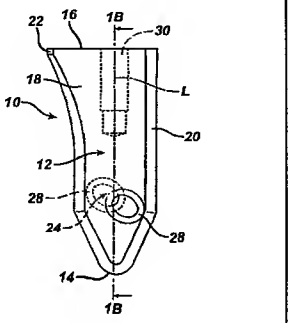

FIG. 1A

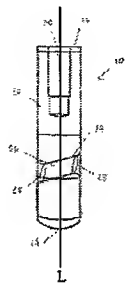

FIG. 1B

Donnelly also discloses methods for attaching soft tissue to hard bone. Col. 1, lines 14-17. A bore 502 is formed in a bone 500 of a patient. Col. 8, lines 17-18. An inserter tool 400 is attached to a bone anchor 410 (although the specification discusses the method with respect to anchor 410, col. 8, lines 3-10 indicates that anchor 10 can also be used in the method) having a suture strand extending therethrough for tapping the anchor 410 into the bore 502. *Id.* at lines 22-28. The suture thread 2 extending from the bone anchor 410 is threaded through a free end of a detached labrum 510 and the bone anchor 410 is tapped into the bore 502 to bring the detached labrum 510 in proximity to the shoulder bone 500. *Id.* at lines 31-36. Once the bone anchor 410 is properly inserted and the detached labrum 510 is in position, the inserter tool 400 can be removed and the free ends of suture thread 2 can be pulled to apply tension to the suture 2 seated within the bone anchor 410 to toggle the anchor to lodge the anchor 410 into the side of the bone cavity 502. *Id.* at lines 48-55. Because the bone anchor 410 has a similar design as anchor 10, and thus its suture channels 424 are ***obliquely angled***, toggling of the bone anchor 410 ***occurs in two planes*** when tension is applied to the suture 2. Col. 4, lines 17-20; *emphasis added.*

b. <u>The Examiner Argues that Donnelly Discloses Each Recitation of the Claimed Method of Attaching Tissue to a Bone in a Patient's Body</u>

The Examiner argues that Donnelly discloses the claimed method of attaching tissue to a bone in a patient's body that includes providing a system for anchoring tissue to bone, the system including a bioabsorbable suture anchor, forming a bone cavity, securing the suture strand to a portion of tissue to be attached to bone, inserting the suture anchor into the bone cavity, and toggling the suture anchor by pulling the suture. Paragraph 8, lines 10-14 on page 3 of the Office

Action. The step of providing a system for anchoring tissue to bone wherein the system includes a bioabsorbable suture anchor includes further limitations directed to limitations that are similar to those discussed with respect to independent claims 1 and 15. The Examiner, relying on *Ex parte Pfeiffer*,[2] however, refuses to give weight to these limitations by arguing that structure limitations must affect the method in a manipulative sense to be entitled to weight in method claims. *Id.* at paragraph 9, lines 15-18.

2. Donnelly Fails to Anticipate Independent Claim 19

Independent claim 19 is not anticipated by Donnelly at least because Donnelly fails to identically disclose a method that includes a suture anchor like the anchor recited in claim 19 because the recitation of the limitations related to the structure of the anchor are entitled to weight in evaluating the method claims and Donnelly fails to disclose such a suture anchor.

a. The Structure Limitations of the Suture Anchor of Independent Claim 19 Must Be Considered

The method of claim 19 recites a step of providing a system for anchoring tissue to bone wherein the system includes a bioabsorbable suture anchor with a suture channel that is oriented substantially transverse at right angles to a longitudinal axis of symmetry of an elongate body of the anchor and having a centerline that is laterally offset with respect to the longitudinal axis of symmetry of the body in a direction opposite to the direction of a flared portion of the anchor. In the Office Action, the Examiner does not argue that Donnelly discloses the configuration of the suture anchor as recited in claim 19, despite arguing such a position in a previous Office Action dated September 20, 2007. *See* paragraph 7, page 4, line 14 to page 5, line 13 of Office Action dated September 20, 2007. This is apparently because the Examiner agrees with the position argued in an Amendment and Response to the previous Office Action dated September 20, 2007, which was submitted on January 22, 2008, that Donnelly fails to disclose a suture channel that is oriented ***substantially transverse at right angles*** to a longitudinal axis of symmetry of an elongate body of the anchor or that has a centerline that is ***laterally offset*** with respect to the

[2] 135 USPQ 31 (Bd. Apps 1961).

longitudinal axis of symmetry of the body in a direction opposite to the direction of a flared portion of the anchor. *See* page 7, line 18 to page 9, line 14 of the Amendment and Response dated January 22, 2008. Instead, the Examiner argues that "[i]t has been held that to be entitled to weight in method claims, the recited structure limitations therein must affect the method in a manipulative sense, and not to amount to the mere claiming of a use of a particular structure. *Ex parte Pfeiffer, 1962 C.D. 408 (1961).*" Paragraph 9, lines 15-18 of page 3 of the Office Action. The claimed method, however, is not a mere claiming of a use of a particular structure, but rather, it is a method of attaching tissue to a bone in a patient's body. Further, the recited structure of the suture anchor ***does affect*** the method in a manipulative sense.

In *Ex parte Kirkland*, a case ruled on by the Board in 1997 in which an Examiner similarly argued that structure limitations must affect the method in a manipulative sense to be entitled to weight in a method claim, the Board found that while one cannot claim a new use per se, ***all limitations of a proper method claim must be considered***. *See* 1997 WL 1883814 *1 (Bd. Pat. App. & Interf.); *emphasis added.* In *Kirkland*, the applicant claimed a method of vending non-beverage foods and non-comestible items from vending machines configured to vend canned drinks. *Id.* While the alleged anticipatory reference disclosed a typical can beverage vending machine, it did not disclose that "the cans vended by the machine are 'filled with a material other than a liquid beverage'" as recited by the method claim. *Id.* The Examiner then cited *Ex parte Pfeiffer* and *Ex parte Kangas*[3] to argue that the contents in the can had no bearing on the manner in which the container is being dispensed from the machine and thus the limitation related to the contents could not be entitled to weight in the method claims. *Id.*

The Board did not consider the rejection well taken. *Id.* First noting that the reference did not disclose, either expressly or inherently, a container filled with a material other than a liquid beverage, the court determined that the reference did not disclose the steps recited in the method claim of "providing at least one container ... filled with a material other than a liquid beverage," "providing a vending machine ... being loaded with said at least one container containing a material other than a liquid beverage," and "vending selectively from said vending

machine said at least one container containing other than a liquid beverage." *Id.* With respect to *Ex parte Pfeiffer* and *Ex parte Kangas*, the Board said the following:

> We do not regard the *Pfeiffer* and *Kangas* decisions as authority for disregarding the recitation in these steps that the container is filled with other than a liquid beverage. Neither *In re Moreton*, 288 F.2d 708, 129 USPQ 227 (CCPA 1961) nor *In re Fong*, 288 F.2d 932, 129 USPQ 264 (CCPA 1961), both cited in *Pfeiffer*, 135 USPQ at 33, supports such a position; rather, they hold that, as stated in *Moreton*, 288 F.2d at 709, 129 USPQ at 228: "since one cannot claim a new use per se, because it is not among the categories of patentable inventions specified in 35 U.S.C. 101, it is claimed as a method, as permitted by 35 U.S.C. 100(b)." In the present case, appellant's claimed invention is, in effect, a new use for known apparatus, i.e., using a canned liquid beverage vending machine to vend cans of non-liquid beverage materials, and ***has been properly claimed as a method.*** We do not consider that in this situation there is any justification for not following the rule that "***all limitations must be considered and that it is error to ignore specific limitations distinguishing over the references.***" *In re Boe*, 505 F.2d 1297, 1299, 184 USPQ 38, 40 (CCPA 1974). When all claimed limitations are considered, [the reference] clearly does not anticipate the appealed claims.

Id. at *2; *emphasis added.*[4] In fact, not considering structure limitations is contrary to the recent holding in *In re Bilski*, in which the Court of Appeals of the Federal Circuit reaffirmed the

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[3] 125 USPQ 419 (Bd. Apps 1960).

[4] *See also, Ex parte Holderness*, 2002 WL 130554, *2 (Bd. Pat. App. & Interf. January 1, 2002) (holding that the placement of graphite into baskets having perforated bottoms plainly affects the claimed method of treating scrap graphite because a basket having a base with a grill or perforations unquestionably would affect how the scrap graphite and particles falling therefrom would be manipulated during practice of the claimed method) and *Ex parte Tuma*, 2006 WL 2791020, *3 (Bd. Pat. App. & Interf. September 26, 2006) (finding a shape of a mold plainly affects the claimed process for producing an adhesive closing part because the claimed shape was important in facilitating removal of the formed adhesive closing part from the mold, even though a step of removing the formed adhesive closing part from the mold was not a recitation in the claim and was only highlighted as an object of the invention).

Supreme Court's machine-or-transformation test, which uses a two-prong test to determine if a process is patent-eligible subject matter under 35 U.S.C. § 101, the first prong of which is whether it is ***tied to a particular machine or apparatus***.[5] Certainly if a process needs to be ***tied to a particular machine or apparatus***, the limitations of the respective machine or apparatus ***must be given weight***.

Similar to *Kirkland*, the claimed method is not an improper use claim, i.e., a method of using a suture anchor system, but rather, is a proper method claim, i.e., a method of attaching tissue to a bone in a patient's body, which is patentable subject matter pursuant to 35 U.S.C. § 100(b).[6] Thus, ***all of the limitations must be considered, and it is error to ignore specific limitations that distinguish over Donnelly***. As discussed briefly above in this section, and as discussed in further detail below in section VII(C)(2)(b) and (c), Donnelly fails to identically disclose a suture anchor having a suture channel oriented ***substantially transverse at right angles*** to a longitudinal axis of symmetry of an elongate body of the anchor and having a centerline that is ***laterally offset*** with respect to the longitudinal axis of symmetry of the body in a direction opposite to the direction of a flared portion of the anchor.

Further, even if the Examiner's position that the structure limitations must affect the method in a manipulative sense is the position of the Board, despite subsequent rulings in cases like *Kirkland*, a person of ordinary skill in the art would recognize that the structure limitations of the suture channel oriented substantially transverse at right angles to the longitudinal axis of symmetry of the elongate body of the anchor and the centerline that is laterally offset with respect to the longitudinal axis of symmetry of the body in a direction opposite to the direction of the flared portion of the anchor ***do affect*** the method in a manipulative sense. As discussed throughout the specification of the present application, as well as the Declaration, the

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[5] __ F.3d __, 88 USPQ 2d 1385, 1391-1392 (2008).

[6] *See In re Kangas*, 125 USPQ 419 (Bd. Apps 1960) (reasoning that 35 U.S.C. § 101 permits patents directed to new and useful processes, and that 35 U.S.C. § 100 provides that a "process" includes "a new use of a known…machine," that "it is implicit in said statutory provisions that claims to a process based on a new use which is otherwise patentable, as in the instant case, are not rendered unpatentable merely because they contain reference to a new machine, as distinguished from a 'known machine.'")

configuration of the suture channel enables a surgeon to toggle the suture anchor by pulling on an attached suture strand while the anchor is inside a bone cavity so that the flared portion toggles into the bone. Paragraph 6, pages 2-3 of the Declaration and page 2, line 19 to page 3, line 13 of the Application. The ability to toggle the suture anchor by pulling on an attached suture strand such that the flared portion of the anchor penetrates into an inner surface of the bone cavity is a recited step in the claimed method, and it is because of the configuration of the recited suture anchor, particularly with respect to its suture channel, that this step can occur.[7] In particular, the transverse bore causes toggling in a single plane, which allows for better placement in small bones by using the recited method. Thus, it is clear that the structure limitations of the suture anchor of the system ***do affect*** the method in a manipulative sense; but for the structure limitations of the anchor, the claimed method could not be performed.

Accordingly, while all of the limitations of the method, including those directed to structures used in carrying out the method, must be considered in determining if a reference anticipates the claimed invention, to the extent that it can be argued that the structure limitations should not be given weight pursuant to *In re Pfeiffer*, the structure limitations of the suture anchor, and in particular the suture channel of the suture anchor, ***do affect*** the method in a manipulative sense and thus should be given weight regardless.

b. Donnelly Fails to Identically Disclose a Suture Channel Oriented Substantially Transverse at Right Angles to the Longitudinal Axis of Symmetry of the Body

The method of claim 19 recites a step of providing a system for anchoring tissue to bone wherein the system includes a bioabsorbable suture anchor having a suture channel that is oriented ***substantially transverse at right angles*** to a longitudinal axis of symmetry of an elongate body of the anchor. As explained above in section VII(C)(2)(a), the Examiner agrees that Donnelly fails to identically disclose a suture channel having such an orientation because the

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[7] *Supra* note 4 (discussing *Ex parte Tuma*, in which a structure limitation was important to an object of the invention, not even a claim limitation as in the present invention, and thus the structure limitation was given weight in the method claims.)

Examiner fails to address previous arguments of this nature and instead argues that the recitations should not be entitled to weight. *See* paragraph 9, lines 15-18 of page 3 of the Office Action. Donnelly certainly does not disclose a suture channel that is oriented ***substantially transverse at right angles*** to a longitudinal axis of symmetry of an elongate body of a suture anchor.

Donnelly discloses a bone anchor that includes a suture channel that is ***obliquely angled*** with respect to a longitudinal axis of symmetry of the body of the anchor. In particular, as shown in FIG. 1B of Donnelly, which is again reproduced below with reference label L added, the suture channel 24 is ***obliquely angled*** with respect to the longitudinal axis of symmetry L of the body. This is completely opposite to the recitation of claim 19, which requires that the suture channel be oriented "***substantially transverse at right angles*** to the longitudinal axis of symmetry of the body" of the anchor.

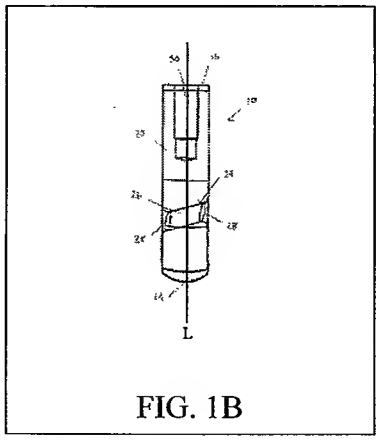


FIG. 1B

In fact, this difference between the teachings of Donnelly and the opposite recitation in the present claims has a purpose: Donnelly seeks to provide a bone anchor that can toggle ***in two planes***. Col. 4, lines 17-20; *emphasis added.* As a solution, Donnelly provides an anchor with an ***obliquely-angled*** suture channel. *Id.*; *emphasis added.* In contrast, the claimed invention is concerned with configuring a suture anchor so as to be suitable for reattaching soft tissue to bone in a small joint such as in the hand or skull. Paragraphs 6 and 7, pages 2-4 of the Declaration and page 2, lines 14-16 of the Application. Claim 19 thus provides a suture anchor having a suture channel oriented ***substantially transverse at right angles*** to the longitudinal axis of the anchor.

Accordingly, at least because Donnelly fails to identically disclose a suture channel that is oriented ***substantially transverse at right angles*** to a longitudinal axis of symmetry of an elongate body of a suture anchor, Donnelly cannot anticipate independent claim 19.

c. Donnelly Fails to Identically Disclose a Suture Channel Having a Centerline that Is Laterally Offset with Respect to the Longitudinal Axis of Symmetry of the Body in a Direction Opposite to the Direction of the Flared Portion

The method of claim 19 also recites a step of providing a system for anchoring tissue to bone wherein the system includes a bioabsorbable suture anchor having a suture channel, the suture channel having a centerline that is ***laterally offset with respect to the longitudinal axis of symmetry*** of the body in a direction opposite to the direction of the flared portion of the anchor. As explained above in section VII(C)(2)(a), the Examiner agrees that Donnelly fails to identically disclose a suture anchor having such a configuration because the Examiner fails to address previous arguments of this nature and instead argues that the recitations should not be entitled to weight. *See* paragraph 9, lines 15-18 of page 3 of the Office Action. Donnelly certainly does not disclose a suture channel having a centerline that is ***laterally offset with respect to the longitudinal axis of symmetry*** of the body in a direction opposite to the direction of the flared portion of the anchor.

The obliquely angled suture channel 24 of Donnelly is ***centered on the longitudinal axis of symmetry L*** of the body. To the extent that Donnelly can be said to provide suture channel openings that are located away from the axis of symmetry, the openings are only so placed because Donnelly lacks a transverse suture channel and provides an obliquely angled one. This is contrary to the recitation of claim 19, which requires that the suture channel have a centerline that is ***laterally offset with respect to the longitudinal axis of symmetry*** of the body in a direction opposite to the direction of the flared portion.

Accordingly, further because Donnelly fails to identically disclose a suture channel having a centerline that is ***laterally offset with respect to the longitudinal axis of symmetry*** of

the body in a direction opposite to the direction of the flared portion of the anchor, Donnelly cannot anticipate independent claim 19.

3. Pedlick Also Fails to Anticipate Independent Claim 19

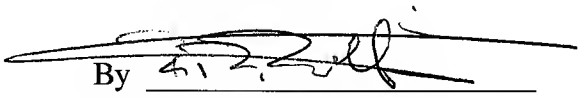
The Examiner states that Pedlick also discloses the method recited in claim 19. Paragraph 13, lines 3-5 of page 5 of the Office Action. At least because Pedlick fails to identically disclose a suture anchor that includes a suture channel having a centerline that is ***laterally offset*** with respect to the longitudinal axis of symmetry of the body in a direction opposite to the direction of the flared portion, Pedlick fails to anticipate claim 19. *See* Section VII(B)(2)(a) above. Further because Pedlick fails to identically disclose a step of toggling the suture anchor ***by pulling on the attached suture strand*** such that the flared portion of the anchor penetrates into an inner surface of the bone cavity, Pedlick fails to anticipate claim 19. *See* Section VII(B)(2)(b) above.

VIII. CONCLUSION

For the reasons noted above, Appellant submits that the pending claims define patentable subject matter. Accordingly, Appellant requests that the Examiner's rejection of these claims be reversed and that the pending application be passed to issue.

Dated: December 8, 2008

Respectfully submitted,



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IX. APPENDIX A: LISTING OF CLAIMS ON APPEAL

1. (Previously Presented) A suture anchor for anchoring tissue to a bone, comprising:

an elongate body defined by a longitudinal axis of symmetry, a first, leading end and a second, trailing end, the elongate body comprising two opposed surfaces between the first and second ends, and a plurality of sidewalls extending between the two opposed surfaces;

a flared portion formed on the second end and extending from one of the sidewalls, the flared portion being adapted to engage and anchor into bone tissue; and

a suture channel formed in the elongate body for passage of a suture strand therethrough, the suture channel extending between the two opposed surfaces, being oriented substantially transverse at right angles to the longitudinal axis of symmetry of the body, and having a centerline that is laterally offset with respect to the longitudinal axis of symmetry of the body in a direction opposite to the direction of the flared portion;

wherein the suture anchor is configured to toggle and anchor inside a bone cavity based on tension being applied to a suture in the suture channel.

2. (Previously Presented) The anchor of claim 1, wherein a length of the elongate body is in the range of about 2 to about 6 mm.

3. (Previously Presented) The anchor of claim 1, wherein a width of the second trailing end is about 1 mm to about 3 mm at its widest portion.

4. (Original) The anchor of claim 1, wherein the first, leading end is tapered.

5. (Original) The anchor of claim 4, wherein the first, leading end extends into a blunt tip having a continuous surface.

6. (Canceled).

7. (Canceled).

8. (Previously Presented) The anchor of claim 1, wherein the suture channel has a chamfered rim.

9. (Previously Presented) The anchor of claim 1, wherein the suture channel has a smooth rim.

10. (Original) The anchor of claim 1, wherein the flared portion has a shape effective to penetrate into bone.

11. (Original) The anchor of claim 10, wherein the flared portion includes a sharp edge.

12. (Original) The anchor of claim 10, wherein the flared portion includes a flat, bone-contacting face with a knife edge.

13. (Original) The anchor of claim 1, further including an insertion tool engaging bore extending into the elongate body from the second trailing end thereof.

14. (Original) The anchor of claim 1, wherein the elongate body is formed with a blue dye for visualization.

15. (Previously Presented) A system for anchoring tissue to a bone, comprising:

a bioabsorbable suture anchor having:

an elongate body defined by a longitudinal axis of symmetry, a first leading end and a second, trailing end, the elongate body comprising two opposed surfaces between the first and second ends, and a plurality of sidewalls extending between the two opposed surfaces;

a bore extending into the elongate body from the second trailing end thereof;

a flared portion formed on the second end and extending from one of the sidewalls, the flared portion being adapted to engage and anchor into bone tissue, wherein the

suture anchor is configured to toggle and anchor inside a bone cavity based on tension being applied to a suture in the suture channel; and

a suture channel formed in the elongate body for passage of a suture strand therethrough, the suture channel extending between the two opposed surfaces, being oriented substantially transverse at right angles to the longitudinal axis of symmetry of the body, and having a centerline that is laterally offset with respect to the longitudinal axis of symmetry of the body in a direction opposite to the direction of the flared portion;

a length of suture thread attached to the suture anchor; and

a suture anchor insertion tool, the tool having an elongate member with a proximal, handle end and a distal, attachment end.

16. (Original) The system of claim 15, wherein the proximal, attachment end of the suture anchor insertion tool includes an insertion tip configured to provide an interference fit with the bore of the suture anchor.

17. (Previously Presented) The system of claim 15, wherein a length of the elongate body is in the range of about 2 to about 6 mm.

18. (Previously Presented) The system of claim 15, wherein a width of the second trailing end is about 1 mm to about 3 mm at its widest portion.

19. (Previously Presented) A method of attaching tissue to a bone in a patient's body, comprising the steps of:

providing a system for anchoring tissue to bone, the system including a bioabsorbable suture anchor having an elongate body defined by a longitudinal axis of symmetry, a first leading end and a second, trailing end, the elongate body comprising two opposed surfaces between the first and second ends, and a plurality of sidewalls extending between the two opposed surfaces, a flared portion formed on the second end and extending from one of the sidewalls, the flared portion being adapted to engage and anchor into bone tissue, wherein the suture anchor is configured to toggle and anchor inside a bone cavity, and a suture

channel formed in the elongate body for passage of a suture strand therethrough, the suture channel extending between the two opposed surfaces, being oriented substantially transverse at right angles to the longitudinal axis of symmetry of the body, and having a centerline that is laterally offset with respect to the longitudinal axis of symmetry of the body in a direction opposite to the direction of the flared portion, the system further including a length of suture thread attached to the suture anchor;

forming a bone cavity in the bone where the tissue is to be anchored;

securing the suture strand to a portion of tissue to be attached to the bone;

inserting the suture anchor at least partially within the bone cavity; and

toggling the suture anchor by pulling on the attached suture strand such that the flared portion of the anchor penetrates into an inner surface of the bone cavity.

20-25. (Canceled).

X. APPENDIX B: LISTING OF EVIDENCE

EXHIBIT A –Declaration of Jose E. Lizardi Pursuant to Rule 132

- Entered by Applicants in Response dated January 22, 2008.
- All references cited in the Declaration can be found in the application file and cited in an Information Disclosure Statement concurrently filed with the Declaration.

XI. APPENDIX C: LISTING OF RELATED PROCEEDINGS

None.

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EXHIBIT A

Docket No. 022956-0214
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:	
Shelby L. Cook et al.	Confirmation No. 9377
Application No. 10/615,625	Art Unit: 3731
Filed: June 27, 2003	Examiner: Tuan Van Nguyen
For: BIOABSORBABLE SUTURE ANCHOR SYSTEM FOR USE IN SMALL JOINTS	

I hereby certify that this correspondence is being sent via EFS-Web to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: January 22, 2008 Signature: _____
(Ronald E. Cahill)

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Declaration of Jose E. Lizardi Pursuant to Rule 132

Dear Sir:

I, Jose E. Lizardi, residing at 3 Kayla Drive, Franklin, MA 02038, hereby declare as follows:

1. I am a joint inventor of the subject matter described and claimed in the above-identified patent application (the Application) and I make this Declaration in support of an Amendment and Response to Non-Final Office Action.

2. I am presently a Staff Engineer in the Research and Development area at DePuy Mitek, Inc., where I have been employed for more than 11 years. I have been working with and developing bone anchors during the entirety of my tenure at DePuy Mitek. Prior to working at

DePuy Mitek, I was employed for approximately four years as an engineer at Smith & Nephew. I worked with and developed bone anchors during the entirety of my tenure at Smith & Nephew as well. My background includes a Bachelor of Science degree in Applied Mathematics and Engineering from the University of South Florida, which I received in 1986.

3. I have read the Application and I fully understand the materials disclosed and claimed therein.

4. The Application is directed to suture anchors, systems, and a method for anchoring tissue to bone that relies on a particular geometry to create directed toggling that is particularly useful in small bones.

5. I have also read U.S. Patent No. 6,270,518 to Pedlick et al. ("Pedlick") and U.S. Patent No. 6,773,436 to Donnelly et al. ("Donnelly"), and I fully understand the inventions disclosed therein. I also understand that the claims of the above-referenced patent application stand rejected as being anticipated by Pedlick, anticipated by Donnelly, and obvious over a combination of Pedlick and Donnelly.

6. The claimed suture anchors are all configured particularly to be toggled inside small bones such as those found in the smaller joints in the body in order to repair soft tissue in those areas. The anchors can be useful in a variety of different procedures, including in the repair or reconstruction of collateral ligaments, flexor and extensor tendon at the proximal interphalangeal (PIP), distal interphalangeal (DIP), and metacarpal interphalangeal (MIP) joints of all digits in a patient's hand, and for attaching soft tissue to the parietal, temporal ridge, frontal, mandible, maxilla, zygoma, and periorbital bones of the skull. They are particularly useful in these types of procedures because of their small size and their geometry. More specifically with regard to the geometry, the suture channel 32 is oriented substantially transverse at right angles to the longitudinal axis of symmetry L of the body 12 and is laterally offset with respect to the longitudinal axis of symmetry L of the body 12 when observed from a centerline of the suture channel 32. The suture channel 32 is laterally offset on the opposite side of the longitudinal axis of symmetry L of the body 32 when compared to the flared portion 24 of the suture anchor 10. This geometry allows the suture anchor 10 to be toggled by pulling on a

strand of suture situated in the suture channel 32 so that the flared portion 24 toggles into the bone, which as illustrated in the embodiment of FIGS. 2A and 2B from the application and reproduced below, would cause the flared portion 24 to toggle in the generally counter-clockwise direction (with respect to FIG. 2A).

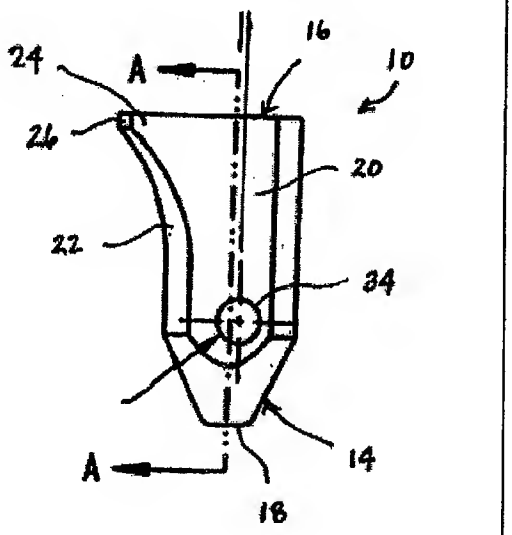
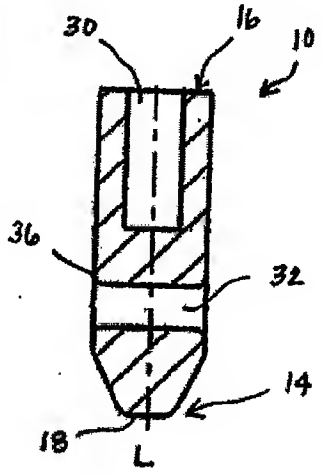


FIG. 2A



SECTION A—A

FIG. 2B

7. Prior to the invention, suture anchors for use in small spaces like those referred to in Paragraph 6, primarily relied upon screws, threads, and barbs to attach tissue to bone. *See at least* U.S. Patent No. 5,522,845 to Wenstrom, Jr., U.S. Patent No. 5,611,814 to Lorenc, U.S. Patent No. 5,950,633 to Lynch et al., *Treatment of Thumb Ulnar Collateral Ligament Ruptures with the Mitek Bone Anchor* by Scott H. Kozin, *Endoscopic Brow Lifts* by Keith F. Brewer, *Biofix® Ligament Tack: Biodegradable Ligament Injury Fixation Tacks Surgical Techniques I* by Pentti Rokkanen et al., *Surgical Technique: Scapholunate Surgical Technique Using the Mitek 2.0 mm Tacit™ Threaded Anchor* by Walter H. Short, *Surgical Technique: Endoscopic Browlift with Rigid Fixation Using the Mitek 2.0 mm Tacit™ Threaded Anchor* by Eduardo Barroso et al., *Product Brochure for the Mitek® 1.3 mm Micro Anchor*, and *Product Brochure for the Mitek®*

2.0 mm Tacit™ Threaded Anchor. While some forms of toggling suture anchors were known for use in large bones prior to the invention, to the best of my knowledge no suture anchors existed that were capable of toggling in such small spaces as the suture anchor of the Application can. This is because the structures in which the suture anchors were used were too small to handle the types of toggling suture anchors that were known. Prior to the Application, it was not known how to design a suture anchor that was small enough to work in those structures and also toggle. Accordingly, those of ordinary skill in the art instead developed non-toggling anchors for use with such small bones, such as anchors with threads and screws.

8. During the same year that the present application was filed, embodiments of the suture anchor as claimed were marketed and sold commercially as both the MINILOK™ and MICROFIX™ suture anchors. It is my understanding that marketing and sales for the suture anchors were performed in the normal course of business. It is also my understanding that the suture anchors have sold well and are still offered for sale today, in particular for uses with surgeries involving the attachment of tissue to bones in the hand and face. Doctors and others purchasing the suture anchors prefer the toggling suture anchors for such use as opposed to the thread or screw suture anchors because the toggling causes less damage to the bone and causes a more secure and exact fit between the tissue and the bone the tissue is being attached to. Ever since the suture anchors were offered for sale in 2003, they have been a success. The commercial success of the suture anchors continue even today as the advantages provided by the first toggling suture anchors for use in small areas such as bones in the hand and face are still realized and appreciated as an industry standard.

9. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true.

Date: 1/18/2008

Jose E. Lizardi
Staff Engineer, Research and Development
DePuy Mitek, Inc.

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